

**AMENDMENTS TO THE DRAWINGS**

The attached sheet of drawings includes changes to Figure. 18. This sheet, which includes Figures 18A and 18B, replaces the original sheet including Figure 18.

Attachments: Replacement Sheet  
Annotated Sheet Showing Changes

### **REMARKS**

This communication responds to the Office Action of November 10, 2009, in which Claim 23 has been rejected under 35 U.S.C. §§ 101 and 112, Claims 1, 22, 41, and 43 have been rejected under 35 U.S.C. § 102, and Claims 36, 42, and 44 have been rejected under 35 U.S.C. § 103. In view of the amendments and the following remarks, reconsideration and allowance are respectfully requested.

#### **Drawing objection**

The drawings are objected to under 37 C.F.R. § 1.83(a) for failing to show every feature of the invention specified in the claims. Amended Figures 18A and 18B are submitted herewith. Full support for new Figure 18B can be found at least in Para. [0067] of Applicants' specification. Withdrawal of the objection is respectfully requested.

#### **Rejection under 35 U.S.C. § 101**

Claim 23 has been rejected under 35 U.S.C. § 101 because it is drawn to non-statutory subject matter. Particularly, Claim 23 has been rejected because Applicants recite part of a human. Claim 23 has been incorporated into amended Claim 1, which now recites "wherein the distal end of the cylindrical body of the first portion is configured to be deformed from its longitudinal axis to abut an outer surface of another one of the multiple fragments," and no longer includes bone fragments as part of the claim. Reconsideration and withdrawal of the rejection are respectfully requested.

#### **Rejection under 35 U.S.C. § 112**

Claim 23 has also been rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. Specifically, the Office asserts that it is unable to find support in the specification or drawings for "the distal end of the cylindrical body of the first portion is configured to be forced radially outwards from its longitudinal axis." As stated above, Claim 23 has been incorporated into amended Claim 1, which now recites "wherein the distal end of the cylindrical body of the first portion is configured to be deformed from its longitudinal axis to

abut an outer surface of another one of the multiple fragments.” Literal support for this limitation may be found at least in Para. [0067] of Applicants’ specification, which recites:

Mandrel 554 includes an enlarged head 558, which enlarged head 558 deforms the distal end of rivet body 552 when mandrel 554 is pulled through rivet body 552 . . . Mandrel 554 is then pulled proximally through rivet body 552 thereby deforming the distal end of the rivet body 552 against the surface of the facet and securing the facets to one another. (Emphasis added).

Thus, reconsideration and withdrawal of the rejection are respectfully requested.

#### **Examiner informal interview**

Applicants thank the Examiner for allowing an informal interview with Applicants’ representative, Nathan Witzany, on February 24, 2010. During the informal interview, the pending method claims and their patentability over the cited references were discussed. The Examiner did not formally agree or disagree with Applicants’ remarks regarding the cited references and requested that Applicant submit the remarks in a formal response for consideration by the Examiner.

#### **Rejection under 35 U.S.C. § 102**

Claims 1, 22, 41, and 43 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Lehmann (U.S. 681,028). Claim 1 has been amended to incorporate the limitations of Claims 22 and 23. In view of the amendments and the foregoing remarks relating to the rejections under 35 U.S.C. §§ 101 and 112, it is believed that Claim 1, including the limitations of Claim 23, is patentable over Lehmann. Claims 41 and 43 have been canceled. Reconsideration and withdrawal of the rejection are respectfully requested.

#### **Rejection under 35 U.S.C. § 103(a)**

Claims 36, 42, and 44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kammerer et al. (US 2001/0010005) in view of Lehmann. As generally discussed during the informal interview of February 24, 2010, Applicants traverse the rejection for at least the following reasons.

Claim 36 is directed to a method for operating a bone fastener used for stabilizing a plurality of bone fragments. The claimed method includes, in part, “displacing a second portion of the bone fastener through and within the first portion such that an enlarged distal end of the second portion abuts the distal end of the first portion, so as to engage the first and second portions of the fastener” and “wherein the curved cylindrical body of the second portion is slidingly disposed within and extending substantially throughout the curved cylindrical body of the first portion.”

Kammerer et al. does not teach nor suggest such a configuration. Particularly, Kammerer et al. does not teach nor suggest “the curved cylindrical body of the second portion is slidingly disposed within and extending substantially throughout the curved cylindrical body of the first portion.” The Office concedes that Kammerer et al. fail “to disclose the device having a first portion and a second portion sliding interlocked relative to one another,” instead relying on Lehman for teaching such a configuration.

However, Kammerer et al. cannot properly be combined with Lehmann because the disclosure of Kammerer et al. teaches away from the structure of the cuff link disclosed in Lehmann and because the proposed modification to Kammerer et al. would improperly change its principle of operation. Kammerer et al. disclose a H-type fastener having a central elongated biasing member with a first and second end. Para. [0011]. Mounted to the first end of the biasing member is a first tissue anchor, and mounted to the second end of the biasing member is a second tissue anchor. Para. [0011]. The elongated biasing member has a resting position, and may be elastically deformed to an extended position. Para. [0011]. In this extended position, the biasing member exerts a biasing force. Para. [0011]. As an example use of H-type fasteners, Kammerer et al. disclose that H-type fasteners and fastening systems are commonly used for non-medical use to affix labels and tags to clothing. Para. [0003].

Kammerer et al. discloses that H-type fasteners may have advantages over conventional fasteners in certain minimally invasive techniques. Para. [0004]. The H-type fasteners are believed to be effective, for example, in meniscal repair since they are relatively easy to insert using a conventional apparatus having a cannulated distal needle. Para. [0005]. Specifically, one tissue anchor of the H-type fastener is loaded into the cannulated needle. Para. [0005]. The

needle is inserted through both sides of the meniscal tear and one anchor is expelled from the needle on one side of the tear. Para. [0005]. The needle is then removed from the meniscus and the other opposed anchor remains in place positioned on the opposite side of the tear, thereby approximating the meniscal tear. Para. [0005]. Accordingly, for specific advantageous reasons, Kammerer et al. disclose only a conventional H-type fastener with an improved biasing member. The H-type fastener may have various resting position configurations, such as saw tooth waves, sine waves, helixes, arcs, parabolas, combinations of straight and curved sections, and the like. Para. [0011]. Nonetheless, as can be recognized from the disclosure and figures, Kammerer et al.'s H-type fasteners are applied and used as one piece, such that they are easy to insert using a conventional apparatus having a cannulated distal needle, as described above.

Lehmann discloses "a link cuff-button which comprises two separable members, one member being composed of a head and a tubular shank on said head, provided with a longitudinal slot having an enlargement, and the other member of a head and a shank provided with a stud for engaging the tubular shank at said enlargement." Lines 19-26; Figs. 2-5. That is, Lehmann discloses a cuff link having two separable members, one with a solid shank which is inserted into a tubular shank of the other. Lines 70-71.

Modifying the H-type fastener of Kammerer et al. by using two separable members, as described by Lehmann, would go against the explicit teachings of Kammerer et al., who disclose only one-piece fasteners for approximating surgical tissue. That is, Kammerer et al. teach away from the use of separable members.

Additionally, one skilled in the art would simply not look to Lehmann's link cuff-button for modifying Kammerer et al.'s surgical tissue fastener, as doing so would change the principle of operation of Kammerer et al.'s device. According to MPEP § 2143.01(VI), the teachings of the references are not sufficient to render the claims *prima facie* obvious if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified. As described by Kammerer et al., its H-type fasteners may have advantages over conventional fasteners in certain minimally invasive techniques. Particularly, Kammerer et al. describe that their H-type fasteners are relatively easy to insert through separated tissue using a conventional apparatus having a cannulated distal needle. Modifying the

H-type fastener of Kammerer et al. with the teachings of Lehmann would result in two separable members, changing the principle of operation of the H-type fastener of Kammerer et al., losing the advantages specifically addressed in Kammerer et al.

Thus, Claim 36 is not made obvious by Kammerer et al. and Lehmann. Claim 42 recites, in part, “displacing a second portion of the bone fastener through and within the first portion such that an enlarged distal end of the second portion . . . wherein the curved cylindrical body of the second portion is slidingly disposed within and extending through more than about 50% of the first portion,” and Claim 44 recites, in part, “displacing a second portion of the bone fastener through and within the first portion such that an enlarged distal end of the second portion . . . wherein the curved cylindrical body of the second portion is slidingly disposed within and extending substantially throughout the curved cylindrical body of the first portion.” Accordingly, for reasons similar to those provided above, Claims 42 and 44 are also not made obvious by Kammerer et al. and Lehmann. Reconsideration and withdrawal of the rejection are respectfully requested.

**Conclusion**

This response is being submitted on or before April 10, 2010, with a request for an extension of time to that date and the associated fee, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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Date: 4/8/10

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